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(71) Applicant: ORAL RESEARCH LABORATORIES, INC. [US/US]; 250 Park Avenue South, New York, NY 10003 (US).

(72) Inventor: GOLDEMBERG, Robert, L. ; 143 West 13th Street, New York, NY 10010 (US).

(74) Agents: SINDER, Stuart, J. et al.; Kenyon & Kenyon & Kenyon, One Broadway, New York, NY 10004 (US).

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(54) Title: COMPOSITIONS FOR THE PROLONGED ACTION OF ANTI-PLAQUE AGENTS

(57) Abstract

The dentifrice compositions comprise compositions which include detersive amounts of an oral surfactant and at least 1 % by weight of a benzoic acid salt or derivative thereof effective to remove plaque from dental surfaces. The combination of the foregoing active ingredients is particularly effective against plaque when used in the compositions of the present invention. The compositions of the present invention include a dentifrice carrier containing at least 1 % by weight of a benzoic acid salt and detersive amounts of an oral surfactant. In a preferred embodiment of the present invention, a toothpaste formulation is provided, which has, as one of its active ingredients, at least about 6 % by weight of a benzoic acid salt. The carrier is any paste, or gel or the like capable of being applied to a toothbrush and brushed onto the teeth. The powder compositions of this invention may be adapted for brushing application onto the teeth in the oral cavity or for use on dentures or other synthetic surfaces outside the oral cavity.

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COMPOSITIONS FOR THE PROLONGED ACTION OF ANTI-PLAQUE AGENTS

Field of the Invention

This is a continuation-in-part application of Serial No. 884,625. This invention relates to improved oral dentifrices and compositions for dental hygiene, and, in particular, to toothpastes and other compositions that enhance plaque removal and prevent plaque buildup.

BACKGROUND OF THE INVENTION

Dental plaque is present to some degree, in the form of a film, on virtually all dental surfaces. It is a product of microbial growth, and comprises a dense microbial layer consisting of a mass of microorganisms that may be embedded in a polysaccharide matrix. The microorganisms present in plaque include coccoidal organisms, among others, particularly in early plaque, which, in the mouths of some persons at least, may change to filamentous organisms after a few days. Plaque itself adheres firmly to dental surfaces and may be removed through a rigorous brushing regimen with

traditional toothpastes and dentifrices. However, plaque rapidly reforms on the tooth surface after it is removed. In fact, plaque constantly changes with time, age, diet, and other conditions.

A wide variety microorganisms are found in the oral cavity, and among these are gram-positive anaerobic rods associated with the development of plaque such as Corynebacterium, Nocardia, Neisseria and Streptococci, such as S. mutens, S. bovis, S. salivarius, and gram-positive streptococci of the genus Peptostreptococcus (See Robert J. Fitzgerald in "The Alabama Journal of Medical Sciences" Volume 5, No. 3, July, 1968, pp. 241-242).

In addition to the aforementioned microorganisms, there is also present in plaque relatively small amounts of other substances such as salivary proteins, carbohydrates, epithelial cells and leucocytes. These organisms play a key role in the etiology of plaque. Some of the bacterial organisms associated with plaque formation produce a capsular material which apparently causes the cells of the organism to adhere to each other, holding the plaque together and allowing for further growth. For example, capsule forming bacteria which occur in large numbers in early plaque are Neisseria sicca and Streptococcus mutans.

Plaque may form on any part of the tooth surfaces, and is found particularly at the gingival

margin, in cracks in the enamel, and on the surface of dental calculus. As discussed in greater detail below, the danger associated with the formation of plaque on the teeth lies in the tendency of plaque to build up, spread, change and eventually produce gingivitis, periodontitis and other types of periodontal disease, as well as dental caries and dental calculus.

More specifically, dental plaque is a precursor to the formation of the hard crystalline buildup on teeth referred to as dental calculus. Both the bacterial and the nonbacterial components of plaque mineralize to form calculus, which comprises mineralized bacteria as well as organic constituents, such as epithelial cells, live bacteria, salivary proteins, leucocytes, and substances having molecularly bound calcium and phosphorus, e.g., hydroxyapatite, $3[Ca_3(PO_4)_2]Ca(OH)_2$ octacalcium phosphate, $Ca_8(HPO_4)_2(PO_4)_4 \cdot 5H_2)$, brushite, $CaHPO_4 \cdot 2H_2O$, and whitlockite, which is considered to have the formula beta-$Ca_3(PO_4)_2$. Dental plaque and, hence, calculus are particularly prone to form at the gingival margin, i.e., the junction of the tooth and gingiva. Supragingival plaque, i.e., plaque that causes damage above the gingival margin, and subgingival plaque, i.e., plaque causing damage below the gingival margine also commonly occur. The buildup of plaque at the gingival margin is believed to be a prime cause of gingivitis and other periodontal disorders.

Regular tooth brushing with a conventional dentifrice for some persons greatly retards or even prevents the accumulation of significant amounts of plaque and calculus. For other persons, however, plaque builds up rapidly even with regular brushing, which, in turn, leads to the formation of calculus, caries, and presents the danger of periodontal diseases. For these people, removal of calculus by a dentist is currently the only safeguard against serious gingival inflammation caused by the accumulation of significant amounts of plaque. A rigorous brushing regimen alone for many individuals, however, will not prevent the formation of significant amounts of plaque.

There is, therefore, a definite need in the art for oral compositions which, when used alone or in conjunction with a regular tooth brushing regimen, are effective to remove and loosen the plaque present on dental surfaces. There is also a need in the art for oral compositions which are effective to remove stains on teeth and dental surfaces.

In view of the foregoing, it is an object of this invention to provide improved dentifrice compositions which exhibit particularly effective detersive action upon plaque, function to loosen and remove plaque present on dental surfaces, and thereby deter the development of calculus and oral diseases associated with excessive plaque formation. It is also an object of this invention to provide dentifrice

compositions effective to remove stains as well as plaque from dental surfaces.

It is a further object of this invention to provide compositions which aid in prolonging the duration of time that dental surfaces are exposed to agents which loosen and remove plaque and prevent the buildup of plaque, for example, lozenges and chewing gums including the active ingredients of this invention.

It is a further object of this invention to provide a dentrifrice cleaning composition effective to remove and loosen plaque and retard the further development of plaque on dentures.

In view of the foregoing, oral compositions containing active anti-plaque ingredients are described herein which, when used in conjunction with a regular regimen of daily toothbrushing, will retard the further development of plaque on dental surfaces. Dentifrice compositions effective to remove stains from dental surfaces are also described in this application.

BRIEF DESCRIPTION OF THE INVENTION

In accordance with the foregoing objectives, this invention provides compositions intended for application to dental surfaces for the purpose of loosening and removing plaque present on the teeth, and retarding the further accumulation of plaque on the treated dental surfaces. In addition, compositions of the pr sent invention are effective to remove stains from dental surfaces (e.g., natural teeth, synthetic

crowns, prosthetic devices or dentures).

The dentifrice compositions of this invention comprise compositions which include detersive amounts of an oral surfactant and at least 1% by weight of a benzoic acid salt or derivative thereof effective to remove plaque from dental surfaces. The combination of the foregoing active ingredients is particularly effective against plaque when used in the compositions of the present invention. The compositions of the present invention include a dentifice carrier containing at least 1% by weight of a benzoic acid salt and detersive amounts of an oral surfactant. The carrier is any paste, or gel or the like capable of being applied to a toothbrush and brushed onto the teeth. The powder compositions of this invention may be adapted for brushing application onto the teeth in the oral cavity or for use on dentures or other synthetic surfaces outside the oral cavity.

By benzoic acid salt we mean any salt which is compatible with the removal of plaque on dental surfaces. In the case where dentifrices or oral uses are made, the benzoic acid should be at least partially water soluble and orally compatible. In the case where the benzoic acid salt is to be used in denture cleansers and other non-oral compositions, the benzoic acid salt should be at least, partially soluble in the solution used to clean the dental surfaces. The particular benzoic acid salt used also must be compatible with the

other ingredients in the composition. Examples of particularly useful benzoic acid salts include potassium benzoate, sodium benzoate, and lithium benzoate. Benzoic acid may also be used. It is to be understood that benzoic acid in solution will form a benzoic acid salt in situ as a function of the pH of the solution.

In further embodiments of the present invention, formulations of the active anti-plaque ingredients include lozenges and chewing gum designed for sustained release of the active anti-plaque ingredients of this invention in the oral cavity over prolonged periods. Such compositions are particularly useful when the brushing of teeth is difficult or impossible.

In preferred embodiments of this invention the dentifrice compositions comprise a gel or paste carrier which includes detersive amounts of an oral surfactant, at least about 1% by weight of sodium benzoate and preferably, an effective amount of dental abrasive. The carrier for the active ingredients may be a gel, paste, powder or the like capable of being applied to a toothbrush and brushed onto the teeth. In other especially preferred embodiments of the present invention formulations of the above anti-plaque ingredients include at least about 6% by weight sodium benzoate.

Clay suspensions may be employed in the dentifrice compositions of this invention. These

materials can have a marked detersive effect on soiled teeth and dentures by aiding the suspension of the active plaque removing ingredients in dentifrice compositions of this invention. In addition clays may function to absorb some of the bacteria loosened by the other ingredients of the dentifrice. A particularly useful synthetic clay material is Laponite XLG™ commercially available from LaPorte Industries, Ltd., London, England, because it can be used to produce dentifrice gels.

Clay material such as kaolin, the bentonites, montmorillonites, china clay, attapulgite and fuller's earth may be useful as abrasives. In addition, a number of insoluble inorganic salts may also be used as abrasives, for example dicalcium phosphate, sodium metaphosphate, calcium pyrophosphate, calcium carbonate, magnesium carbonate, and silicates or silicic acid and derivatives thereof, for example, abrasive silica, xerogel, and precipitates. Many of these abrasive compounds are particularly useful in promoting stain removal in embodiments of the present invention. It is to be understood that the abrasives should be compatible with the use of soluble benzoic acid salts, and certain abrasives are to be avoided where their use will result in precipitated or marginally soluble salts of benzoic acid.

In further embodiments of the dentifrice of this invention, a substantive biocidal agent is employed

to enhance the control of plaque. For instance, Johnson et al. report in "A Review of Chemotherapeutic Plaque Control", ORAL SURG. 47(2): 136-141 (Feb. 1979) that the biguanide chlorhexidine has been demonstrated to successfully control plaque. As is explained in greater detail below, the effectiveness of plaque inhibiting compositions can be enhanced by adding one or more substantive biocides in addition to any other biocides present in the formulation. It must be noted that the use of a substantive biocide must be compatible with certain active ingredients in the compositions of the present invention. Specifically, when an anionic surfactant is to be used in certain embodiments of the present invention, it is preferred that the substantive biocide be avoided.

In further embodiments of the dentifrice of this invention, effective amounts of sodium monofluorophosphate or sodium fluoride may be used to aid in preventing dental caries. This activity is in addition to the separate anti-caries activity which is believed to result from the use of the compositions of this invention to remove plaque from dental surfaces.

In further embodiments of the dentifrice compositions of this invention, minor effective amounts of colorant, flavorant, antiseptics, healing agents and other additives are preferably employed in combination with the other ingredients. More specifically, formulations of the dentifrice of this invention may

include antiseptically effective amounts of sodium salicylate, an antiseptically active flavorant, e.g., thymol/eucalyptol menthol and a healing agent such as allantoin. Of course, the benzoate salt itself imparts antiseptic properties to the formulation. Compositions containing the foregoing ingredients may serve to sooth gums irritated from brushing, and to actually enhance the rate of healing of gums and associated tissues which may have become irritated during brushing or are due to an existing periodontal disorder such as gingivitis.

Other ingredients which may be employed in the present invention include humectants, emulsifiers and bulking agents which can be added to disperse the active ingredients throughout the compositions. In the case of gels and pastes, these humectants and bulking agents aid in providing a gel-like texture to the toothpaste or gel compositions. In the case of tooth powders the preferred bulking agents used are organic acids and salts derived therefrom, salts of phosphate, and other buffers, designed to provide bulk and a buffering effect without forming a gel. Orally compatible polyhydric alcohols such as sorbitol, mannitol, and hydrogenated starch hydrolysates, for example lycasin™ (available from Poquette Freres, France) are also preferred as bulking agents. These humectants/emulsifiers and bulking agents act to disperse the active ingredients within the dentifrice composition to provide effective anti-plaque activity by maintaining the concentration of

the active ingredients at effective levels throughout the formulation.

The dentifrice of this invention may be applied to the surface of the teeth by any conventional process, but preferably through the use of a conventional toothbrush. The dentifrice is preferably applied by placing a comfortable amount of the dentifrice on a tooth brush and then brushing the dentifrice about the teeth and gums with the intention of thoroughly exposing all surfaces of the teeth to the dentifrice of the present invention.

In further embodiments of this invention, an amount of a benzoic acid salt and oral surfactant effective to loosen plaque will be incorporated into a chewing gum or lozenge carrier. These compositions are designed to administer the active anti-plaque ingredients onto the teeth for a sustained period of time, e.g., when brushing is difficult or impossible. In addition, these formulations are designed to take advantage of the natural jaw and tongue movement that occurs when chewing gum and lozenge vehicles are used. This movement may aid in uniformly dispersing the active agents of the composition about the dental surfaces.

It is preferable that the active anti-plaque ingredients be uniformly dispersed in the chewing gum and lozenge vehicles of the present invention. Uniform dispersal of the active ingredients will result in substantially uniform amounts of the active ingredients

being released over a prolonged time period. This will increase the duration of time that the teeth will be exposed to the actives and also maximize the likelihood that the active ingredients of the composition will loosen plaque on dental surfaces hard to reach through brushing, e.g., the areas between the teeth normally reached only by flossing. In this manner, these compositions can function as an adjunct to flossing.

In other preferred embodiments of this invention, the chewing gum comprises a gum-base carrier, having distributed therein effective amounts of an orally compatible surfactant, and at least about 1% by weight of a benzoic acid salt. An active anti-plaque substantive biocide, for example, the biguanide chlorhexidine, may also be included in other preferred embodiments of the chewing gum. Of course, the substantive biocides will also be useful with additional compatible ingredients.

In preferred embodiments of the lozenge, effective amounts of the aforementioned active ingredients are combined with a lozenge carrier compatible with the benzoic acid salt and oral surfactant components. For example, the lozenge vehicle may be a conventional lozenge base prepared from a tableting lubricant or plasticizer such as glycerine or polyethyleneglycol and powdered sorbitol or a natural or synthetic gum such as gum acacia, tragacanth, guar, psillium and others. It is preferred that enough water

be added so that the formula can be partially solubilized, and formulated to be malleable enough for forming a mass, rolled out in a dough-like form and then cut with an appropriate cutter. Lozenges can also be formulated utilizing powdered sorbitol or a natural or synthetic powdered gum. The ingredients to be included may be thoroughly mixed as powders and then compressed, using a tablet forming compression machine. As will be recognized by those of ordinary skill in the art, flavorants, e.g., artificial, non-cariagenic sweeteners such as aspartame, saccharine, cyclamates, and colorants, texturizers, or the like may be employed to impart the desired flavor or color to the lozenge and the other compositions of this invention.

In further embodiments of the chewing gum and lozenge aspect of this invention, binders, fillers, and plasticizers are added to produce compositions with the desired uniformity of release of actives by maximally dispersing the active ingredients throughout the delivery vehicle. The plasticizers aid to maximize the workability and solubility of the actives in the chewing gum and lozenge base. It is preferred that actives be in a form which can readily solubilize when exposed to saliva without being released too quickly from the release matrices. The plasticizers useful in this invention are added to provide the n cessary dispersability and solubility of the actives without disturbing the effects of the chewing gum and lozenge

release matrix.

In further embodiments of the chewing gum and lozenge aspects of this invention, sweeteners, flavorants, colorants, antiseptics, healing agents, and other additives may be advantageously employed to produce a pleasantly palatable formulation with gum healing and soothing activity. More specifically, chewing gum and lozenge compositions of this invention may include antiseptically effective amounts of sodium salicylate and an antiseptically active flavorant for example, thymol eucalytol menthol.

Natural and artificial sweeteners may also be employed. It is preferred that non-cariagenic sweeteners, for example, saccharin, aspartame, cyclamates or blends of saccharin and aspartame, be used in embodiments of the present application. These non-cariagenic sweeteners provide beneficial flavor characteristics to the chewing gum and lozenge, i.e., promote compliance to use these vehicles, but do not promote the growth of plaque. Cariagenic sweeteners, for example glucose, sucrose, fructose, corn syrup and others well recognized in the art may also be employed in embodiments of the chewing gum formulations. Though useful, these cariagenic sweeteners are less preferred than non-cariagenic sweeteners because they provide nutrients which aid the growth of plaque. Additional non-cariagenic bulk sweeteners that are less potent than the above-mentioned intensive sweeteners, may also be

used for example, glycerine and sorbitol.

The chewing gum of this invention is used in a traditional fashion i.e., by chewing the gum and moving it about the teeth by natural jaw and tongue movement with the intention of releasing the actives at a sustained rate for a prolonged period of time from the chewing gum matrix. The lozenge is also utilized in a traditional manner, i.e. by slowly dissolving the tablet in the mouth and washing the teeth with the actives by moving the tongue about the mouth. The chewing gum and lozenge compositions of this invention can also be used as the pre-brushing step in conjunction with mouthwash formulations, for example, as described in U.S.S.N. 692,821 of Goldemberg, et al. which is incorporated by reference herein.

The pH of the compositions of the present invention should be controlled within a particular range of about 4.0 to 10.0 to promote the activity of the anti-plaque compositions of the present invention. In compositions embodying the present invention, it will be preferred to employ a pH in the range of about 5.5 to 8.0, and is most preferable to employ a pH range of about 6.0 to 7.0. However, to some extent pH may have to be adapted to the other components, for example, the presence of carbon dioxide releasing components in certain embodiments of denture cleansers.

In further embodiments of this invention, plaque loosening amounts of a benzoic acid salt and a

surfactant may be incorporated into compositions for cleaning surfaces, for example dentures or synthetic or porcelain surfaces outside the oral cavity. Denture cleaning compositions are provided in tablet or powder form for addition to water where the surfaces are cleaned. These compositions comprise a surfactant and amounts of a benzoic acid salt effective to remove plaque.

In embodiments of the denture cleanser of this invention, the formulation may comprise, in addition to a surfactant and effective amounts of salts of benzoic acid, substantive biocides, for example, chlorhexidine, its derivatives and pharmacologically acceptable salts or esters thereof such as 1, 1'- hexamethylene bis- [5- (4- chlorophenyl) biguanide digluconate. Additionally, salts of perborate or persulfate can be employed such as sodium perborate or sodium persulfate as well as other compounds known to release hydrogen peroxide or other oxidizing agents upon exposure to acidic or basic solutions. These compounds upon release of oxidizing agents after exposure to solution serve to aid the plaque removing ingredients.

Further embodiments of the denture cleanser may incorporate disinfectants/antiseptics in combination with the other ingredients. More specifically, formulations of the denture cleanser may include effective amounts of sodium salicylate and sodium borate (borax). Compositions of the present invention may also

include sodium borate as a detergent builder, to enhance the detersive effects of the surfactant in the pH range of about 7.0 to 10. Acidic pH ranges may be useful in certain embodiments, depending on the additives that are used. Further preferred embodiments of the denture cleanser may include a combination of an organic acid, for example citric, acetic, malic or tartaric, among others, and salts of bicarbonate. A preferred organic acid, citric acid, is employed to lower the pH of a solution containing the composition to the acidic range and to buffer the aqueous solution. Salts of bicarbonate are employed in combination with citric acid to provide an effervescent quality to the cleanser. The effervescence provides a physical mixing of the active ingredients which further enhances the anti-plaque effects of the composition. Of course, any compatible gas emitting substance that produces effervescence upon exposure to a solution can be used. A number of additional ingredients utilized in the other aspects of the present invention can also be used, levels depending on the pH and the compatability of the additional ingredients employed.

The denture cleanser of the present invention may be applied in solutions outside of the mouth. Preferably, the dentures are placed in contact with cleanser solution for as short a time as a few minutes, or alternatively, for a few hours or overnight.

Further objectives of this invention will be

apparent from the detailed description of the invention which follows.

DETAILED DESCRIPTION OF THE INVENTION

The dentifrice composition of this invention comprise detersive amounts of an oral surfactant, and at least about 2 percent of an orally compatible salt of benzoic acid in a gel, paste, powder or liquid vehicle. Preferably, dentifrice compositions of the present invention comprise at least about 6% by weight of an effective benzoic acid salt and most preferably between about 6% and 10% by weight of a benzoic acid salt. A gel carrier is a preferred vehicle of administering the active anti-plaque agents. A gel carrier is any group of non-active ingredients that functions to aid introduction of the active ingredients onto the teeth and gums. The gel carrier may include water or a solution of water and alcohol (ethanol). Where employed, the gel carrier may comprise from about 5% to about 98% by weight of the composition but preferably comprises about 65% to 95% by weight of the compositions.

The oral surfactants employed in the dentifrice, chewing gum and lozenge compositions of this invention are those which are nontoxic and therefore suitable for use in the oral cavity. These provide a detersive effect when they are applied during regular tooth brushing. As explained below, it is preferable to employ a silica, xerogel or silica precipitate

abrasive in combination with the oral surfactant but only in the dentifrice compositions of the present invention.

The oral ionic surfactants are preferred for use as the oral surfactant component, and suitable non-ionic, anionic, amphoteric and cationic surfactants may be employed in the dentrifrice, chewing gum and lozenge formulations. In fact, any surfactant exhibiting strong detersive properties can be used. Denture cleansers of the present invention may employ any number of surfactants, but the oral surfactants are preferred because they may minimize any damage to the surface of the dentures. Suitable oral anionic surfactants for use herein include alkyl sulfates such as the soluble nontoxic salts of lauryl sulfate and alkyl sulfonates such as sodium lauryl sulfonate or other sulfonates of alcohols having about 10 to about 18 carbon atoms, as well as N-methyl- N-palmitoyl tauride, or sodium-N-lauroyl sarcosinate or the like. Certain of the anionic surfactants may not be compatible with certain substantive biocide compositions useful in embodiments of the present invention.

Nonionic oral surfactants which also may be employed herein include mixtures of fatty acid esters of sorbitol and sorbitol anhydrides consisting predominantly of the monoester condensed with about 15 to 25 (e.g. 20) moles of ethylene oxide, such as the commonly available nonionic detergent Tween 20 available

from I.C.I. Americas, Wilmington, Delaware. Other block co-polymers of polyoxyethylene and polyoxypropylene, such as Pluronic F108 available from BASF- Wyandotte Co., Wyandotte, Michigan are useful as well. Other non-ionic organic surface active compounds which are contemplated for use in the present invention include products derived from alkylene oxide condensed with hydrophobic compounds, such as long chain aliphatic alcohols, alkylphenols, carboxamides, sulphonamides, fatty acid amides, and oxyalkylated alcohols. These agents may also function as emulsifiers, humectants and dispersants to provide maximal anti-plaque effect by maintaining the concentration of the active ingredients at anti-plaque levels throughout the dentifrice chewing gum and lozenge composition. An additional preferred non-ionic surfactant is polysorbate.

Additional surfactants, including cationic and amphoteric surfactants may also be employed in embodiments of the present invention, provided that compatability requirements with additional agents added to the forumulations are maintained. The level of surfactant will, of course , depend on the desired characteristics of the compositions.

The oral surfactant is preferably employed in the paste, gel, powder, chewing gum and lozenge compositions of the present invention at levels ranging from about .1% to about 10% by weight of the composition, and most preferably from about 0.5% to

about 6% of the composition. However, in general, the nonionic detergent is employed at levels sufficient to provide the desired degree of detersive effect or, if desired, foam in the oral cavity during use.

The compositions of this invention may also include effective amounts of a compatible substantive biocide. Preferred substantive biocides for use herein, include the bisguanide, chlorhexidine, its derivatives, and pharmacologically acceptable salts or esters thereof, such as 1,1'-hexamethylene bis -[5-(4-chlorophenyl) biguanide] digluconate. The substantive biocide preferably comprises about 0.005 percent to about 0.75% by weight of the composition. In general, depending on the substantive biocide employed, anionic surfactants are generally not included because of compatability problems. For example, chlorhexidine and sodium lauryl sulfate are generally not used in combination.

An abrasive is employed in combination with the oral surfactant component of the dentifrice formulations to aid in the removal of stains and plaque on teeth. The abrasive compounds used in compositions of the present invention are non-toxic, and orally compatible. A number of inorganic salts can be used as abrasives, for example dicalcium phosphate, sodium metaphosphate, calcium pyrophosphate, calcium carbonate, magnesium carbonate, hydrated aluminum oxide, silicates and silicic acid and derivatives thereof. In

formulating th compositions of the present invention, care must be taken to avoid the formation of calcium and other insoluble salts of benzoic acid.

A number of clay materials, for example kaolin, the bentonites, montmorillonites, china clay, attapulgite and fuller's earth, may be also used as abrasives but the addition of these clay materials may make the clear toothpaste gel form extremely difficult to produce. In preferred embodiments dehydrated silica precipitate abrasives such as Zeodent™, or Zeo49™ (J.M. Huber Corp., Chemicals Division, Etowaha, Tenn.) or a silica xerogel abrasive, for example Syloid 74™ (Davison Chemical Division of W.R. Grace Co., Baltimore, MD) are used in the dentifrice compositions because these can be used without affecting formation of gels. In preferred embodiments, between about 5 and about 25 percent abrasive by weight of the dentifrice composition is used.

Other ingredients which may be employed in the gel carrier composition of the present invention include those which can be added to provide bulk and gel-like texture to the dentifrice. Formulations of the present invention may include a fumed silica precipitate such as Zeosyl 200™, Zeothix 265™ (Huber) or a natural or synthetic clay material such as Laponite XLG™ (LaPorte Industries, Ltd., London, England) or Veegum™ (R.T. (R.T. Vanderbilt, Co., Inc., Norwalk, Conn.) which aid gelling and bulking of the dentifrice, as well as the

dispersal of the active ingredients in the dentifrice.

Bulking and binding agents useful in the dentifrice powders, pastes, gels, chewing gum and lozenge include the natural and synthetic gums such as carboxymethyl cellulose, xanthan gum, gum tragacanth, algin, carrageenan, pectin, gum acacia, karaya, locust bean gum, gum arabic, guar gum, psillium, guince, tamarind and larch. Ingredients such as sorbitol that function both as emulsifiers and dispersants may also be employed. Sorbitol is especially useful in formulating lozenges. When sorbitol is used it may comprise about 3% to about 99.5% by weight of the lozenge. These bulking agents help to disperse the active ingredients within these compositions to provide maximal anti-plaque effect by maintaining the concentration of the ingredients at active levels throughout the composition.

Plasticizers may also be employed in the compositions of this invention to aid in maximizing the "workability" of the composition of dental surfaces. The amount of plasticizer used will be adjusted on the basis of the desired degree of plasticization, other ingredients of the formulation, etc. Any orally compatible plasticizer that is also compatible with the active agents of the formulations of the present invention may be employed. Examples of such plasticizers include the polyethylene glycols, glycerine, and ethyl alcohol. In the case of chewing gums, in addition to the foregoing, other plasticizers

such as lanolin, stearic acid, sodium and potassium stearate may also be useful, for example, in the range of about 1% to about 30% by weight as well as lecithin, hydrogenated coconut oil, hydrogenated cottonseed oil, mineral oil, olive oil, candelilla wax, paraffin and beeswax.

In preferred embodiments of this invention, sodium benzoate is preferably employed at a level of at least about 1% by weight, and more preferably at a level of at least about 2% by weight of the composition. In the case of dentifrice compositions, it is also preferable to employ sodium benzoate at a level of at least about 6% by weight and most preferable to employ sodium benzoate within a range of about 6% to about 10% by weight.

Plaque consists of about 80% live bacteria in a polysaccharide matrix. It is therefore desirable for a dentifrice to possess significant antibacterial properties in order to eliminate or retard the growth of the bacterial colonies present in plaque. The relatively high levels of sodium benzoate employed in embodiments of this invention impart antiseptic properties to the composition. Moreover, in order to advantageously enhance the antiseptic properties of the compositions additional antiseptics may be included.

A preferred, antibacterial (and analgesic) additive is sodium salicylate. In addition to, or in place of sodium salicylate, other oral antiseptics which

are compatible with the other ingredients of the composition may be employed, for example, benzethenium chloride, N-alkyl- pyridinium chloride, N-cetyl pyridinium bromide, sodium N- lauroyl sarcosine, N-myristoyl glycine and potassium N-lauroyl sarcosine. The sodium salicylate or other analgesics preferably comprise about .1 to 6%, and most preferably, about .2 to about 1.0% by weight of the compositions.

The composition of this invention may also include adjuvant ingredients effective to provide the desirable flavoring and coloring, and to impart the desired mouthfeel to the composition. In further embodiments of these compositions, the flavorant employed is one which possesses antiseptic properties, e.g. a flavorant based upon thymol, eucalyptol and/or menthol. Thus, the composition may include the combined antiseptic ingredients sodium benzoate, sodium salicylate and the above-mentioned antiseptic flavorant or an equivalent antiseptic flavorant. The concentration of the flavorant is adjusted to impart the desired taste and/or degree of antibacterial activity to the overall formulation. In further preferred embodiments alcohol SD38B is employed as a carrier for the flavorants. In the formulations of this invention, flavorants comprise about 0% to about 4% by weight.

Sodium bicarbonate may advantageously be employed in the compositions of this invention for purposes of buffering the pH and building the detersive

effects of the oral surfactant.

The compositions of this invention may also contain humectants such as glycerine in amounts up to about 50% by weight, or, for example, about 5% to about 45% by weight. The glycerine functions as a sweetener, and imparts body to the compositions as well as the desired mouthfeel. Equivalent materials may be employed in place of, or in combination with glycerine such as sorbitol propylene glycol, and polyethylene glycol.

The dentifrice is prepared by mixing the active ingredients together to form a homogeneous gel, paste, or powder of the constituent ingredients. The dentifrice is used in a conventional manner, that is, by applying a comfortable amount to the toothbrush, and brushing it about the dental surfaces.

In embodiments of the chewing gum of this invention,the same active ingredients used in the dentifrice formulations may be used. The chewing gum compositions require a chewing gum base preferably comprising about 5% to about 75% by weight of the final chewing gum product. The ingredients referred to as a gum base comprise typical natural and/or synthetic masticatory substances known to the art, for example chicle, crown gum, nispero, rosidinha, jelutong, pondare, tunu, gutta, perillo, synthetic polymers for example polyethylene, polyisobutylene, polyvinylacetate, paraffin, petroleum wax, butadiene-styrene polymer, and isobutylene-isoprene copolymer.

Other preferred embodiments of the chewing gum of this invention include the aforementioned binders, fillers, sweeteners and flavorants. Preferred binders for the chewing gum include the aforementioned natural and synthetic gums gum acacia, carboxymethyl cellulose and other cellulose derivatives both natural and synthetic, algin, carageenan, pectin, tragacanth, karaya, locust bean gum, gum arabic, guar gum, psillium, quince, tamarind and larch.

When binders are used in the chewing gum compositions of this invention, they preferably comprise about 2% to about 80% by weight. A particularly useful binder is preferably comprised of a mixture of about 30% to 70% by weight gum acacia in water. Preferred fillers useful in the chewing gum of this invention include but are not limited to sorbitol, mannitol or combinations of these ingredients. Preferably, a filler or bulking agent when used, comprises from about 4% to about 90% by weight and most preferably comprises about 5% to about 75% by weight. A particularly useful combination is comprised of a solution of about 10% to about 80% sorbitol in water and preferably about 45% to about 70% by weight sorbitol in water.

The addition of binders and fillers is important to the sustained administration of the anti-plaque ingredients onto the teeth. The amount of binders and fillers utilized will often determine the rate at which the actives are solubilized by saliva and

leach out of the chewing gum matrix to make contact with the plaque.

In other preferred embodiments of the chewing gum compositions flavorants are added. The preferred flavorant includes the aforementioned combination of thymol eucalytol and menthol. Other preferred flavorants useful in the chewing gum include flavorants well-known in the prior art, for example spearmint, peppermint, fruit flavors, etc. Preferably the flavorant should comprise about 0.005% to about 5% by weight of the chewing gum. Preferably, sweeteners are also included in preferred embodiments of the lozenge. Preferred sweeteners are those which are non-cariagenic i.e., do not promote the growth of plaque by serving as nutrients. Preferred non-cariagenic sweeteners include aspartame, salts of saccharin, and other intense sweeteners. The amount of sweeteners added depends on the taste desired and the other ingredients added, but usually the sweetener comprises about 0.001% to about 1% by weight. Natural, cariagenic sweeteners may also be utilized, but are not preferred. When used, natural cariagenic sweeteners comprise about 5% to about 98% by weight of the compositions. Non-cariagenic bulk sweeteners, for example glycerine or sorbitol may also be utilized.

To prepare a typical chewing gum composition, the gum base is prepared by heating and blending the various ingredients in a manner well-known in the art.

To provide maximum dispersal of the activ ingredients it is preferred that the actives be dissolved or solubilized by plasticizer or water to produce a highly concentrated solution and then the resulting solution added to the gum base.

The chewing gum compositions of the present invention are used in a conventional manner, i.e. by inserting gum into the mouth and moving the gum about the teeth using jaw and tongue movement. The chewing gum compositions can be used in conjunction with a conventional tooth brushing or other oral hygiene method, or as a pre-brushing step. In addition, the gum can be utilized during "difficult to brush" times to aid in loosening, removing, and preventing plaque buildup.

In embodiments of the lozenges of this invention, the same active ingredients used in the dentifrice and chewing gum compositions are used. It is preferred that artificially sweetened or sugarless lozenges be formulated. In sugarless lozenges, large amounts by weight of binders and/or fillers are generally used. The preferred binders and/or fillers include sorbitol, mannitol and a number of natural gums preferably for example gum acacia and tragacanth, karaya, or guar gum. In sugarless lozenges, binders and/or hydrogenated starch hydrolysate fillers comprise about 40% to about 97.7% by weight.

The lozenge formula is also preferably comprised of a plasticizer or tableting lubricant for

example polyethylene glycol, glycerine and other materials aforementioned. The plasticizer which aids the mixing and dispersing of the active ingredients before the formulation is tableted preferably comprises about 0.005% to about 5% by weight. In addition, small amounts of water, preferably about 0.02% to about 5% are added to aid mixing before formulation into tablets.

The lozenge composition may also be sweetened naturally or artificially with for example, sucrose, corn syrup, saccharin or aspartame. When lozenges are formulated using natural sweeteners, the sweeteners may comprise about 40% to about 97.7% by weight of the lozenge. When artificial sweeteners are used, these comprise about 0.005% to about 1% by weight. The same flavorants and amounts of flavorants used in the chewing gums may be used in the lozenge compositions.

To formulate lozenges, effective amounts of the active ingredients are combined with a tableting lubricant for example polyethylene glycol, glycerine, or sorbitol or a natural or synthetic gum such as gum acacia or tragacanth. When lozenges are to be prepared by rolling and cutting, enough water or plasticizer must be added to allow the formula to become dough-like so that it can be rolled and then cut into lozenges. This amount usually is about 0.5% to about 10% by weight of the composition.

Alternatively, lozenges can be formulated utilizing powdered sorbitol or a natural or synthetic

gum. The ingredients to b formulated are thoroughly mixed in powder form and then compressed using a tablet forming compression machine.

Lozenges of the present invention are utilized in a conventional manner, i.e. by slowly dissolving in the mouth upon exposure to saliva. The active ingredients bathe the teeth and can reach hard to reach surfaces by being washed about the teeth by the tongue of the user. These formulations can also be used in conjunction with a usual toothbrushing or oral hygiene method. The lozenges of the present invention can be used before brushing with a conventional toothbrush or after brushing to aid in the removal and prevention of plaque buildup.

In embodiments of the denture cleanser the same surfactants used in the oral dentifrice may be used. Of course, surfactants other than orally compatible surfactants can be used, but it is preferred that oral surfactants be used to maximize plaque removal without damaging the denture surfaces. Sodium lauryl sulfate is a particularly preferred oral surfactant useful in this invention. Surfactants are useful in a range from about 0.1% to 10% by weight of the composition, and are most preferable in a range of about 0.5 to about 10% of the composition. Of course, the amount of surfactant can be adjusted to provide the desired detersive action.

Salts of benzoic acid or benzoic acid

analogues are also used in the denture cleanser aspect of this invention. At least about 1% by weight of a salt of benzoic acid or an analogue of benzoic acid is useful, and preferably at least about 4% to about 15% by weight of sodium benzoate is used. A nascent oxygen containing compound is preferably included in compositions of the denture cleanser of the present invention to aid in removing stains present on dentures. In certain preferred embodiments of the denture cleanser, salts of perborate and/or persulfate are used in the range of from about 2% to 25% by weight and preferably about 5% to about 17% by weight. Any water soluble perborate or persulfate salt can be used in the composition, but it is preferred that sodium perborate or persulfate be used.

In further preferred embodiments of the denture cleanser antiseptics , such as those previously described herein, for example salicylate, as well as other ingredients for example, salts of boric acid and allantoin are added to the formulations. Any effective amount of sodium salicylate can be used, but it is preferred that sodium salicylate be used in a range from about 0.2 to 6% by weight. It is preferred that the sodium salt of borate be used at a concentration from about 0.2 to 10% by weight. In preferred embodiments, allantoin can be used at a concentration of about 0.1% to about 3% by weight of the composition to disperse the protein film of plaque and aid plaque removed.

An organic acid and a compatible gas releasing composition are preferably employed in combination to provide an effervescent quality to solutions of the denture cleanser. Preferable organic acids that may be employed in the denture cleanser of this invention include acetic acid, citric acid, malic acid, and tartaric acid, among others. Citric acid is most preferred. The organic acid should be employed in concentrations sufficient to lower the pH of aqueous solutions of the dental cleanser sufficiently to release carbon dioxide from a gas releasing composition such as a salt of carbonic acid or bicarbonate.

In many compositions of the present invention, the pH is in the range of about 4.0 to about 10. It is preferred that a pH of 5.5 to 8.0 be utilized and most preferable at a pH of 6.0 to 7.0 be used. The pH of course, may be higher or lower depending upon the other components of the compositions employed. In certain embodiments of denture cleansers the pH may have to be lowered to accommodate gas releasing components. Sodium bicarbonate is the preferred gas- releasing component. The preferred concentration of sodium bicarbonate is that which provides sufficient effervescent activity in combination with citric acid to create a mixing action which aids plaque removal, preferably about 20% to about 50% by weight. In addition, in preferred embodiments of the dentifrice compositions of the present invention, a pH of between about 5.5 and 8 is preferably employed,

though any pH compatible with oral use may be utilized.

Bulking agents can also be used in certain preferred embodiments, along with buffers and preservatives. A particularly effective compound exhibiting bulking and buffering, activities is trisodium hydrogen phosphate, but any of the water soluble phosphates may be used. Additionally a large number of neutral salts can function as the bulking agent, for example sodium and potassium chloride.

The denture cleanser may be prepared by mixing the active ingredients into a homogeneous powder. The powder may be packaged and used as such, or may be formulated in pre-measured tablet form. The denture cleanser is used in a conventional manner; that is, by dissolving a recommended quantity in water, and exposing the dentures to the solution for a period sufficient to clean the dentures and remove plaque, generally overnight.

The manner of making and using the present invention will be illustrated further by the following detailed examples.

EXAMPLE 1 - GEL DENTIFRICE

NO.	PHASE	INGREDIENT	% BY WEIGHT
1	A	GLYCERINE 96%	14.00
2	A	CARBOXYMETHYL CELLULOSE (CMC 9M31XF-HERCULES)	0.30
3	B	SORBITOL 70%	41.83
4	B	XANTHAN GUM (KELTROL T)	0.03

5	B	ALLANTOIN	0.2
6	B	SODIUM BORATE	0.2
7	B	SODIUM BENZOATE	2.0
8	B	SODIUM SALICYLATE	0.2
9	B	SODIUM MONOFLUORO-PHOSPHATE	0.83
10	B	SODIUM SACCHARINE	0.3005
11	B	DEIONIZED WATER	5.00
12	B	CARBOWAX 1540	5.00
13	C	SILICA ABRASIVE ZEO 49	14.00
14	D	SILICA GELLANT ZEOTHIX 265	7.25
15	E	GLYCERINE 96%	5.50
16	E	SODIUM LAURYL SULFATE	1.00
17	E	FLAVOR	0.90
18	E	ALCOHOL SD38B	1.00
19	E	D&C RED #40 (1% aqueous)	0.45
	TOTAL		100.00%

Procedure: Carboxymethyl cellulose is sprinkled into glycerine in the amounts listed with agitation until fully mixed. This is Phase A. In a separate vessel phase B ingredients except Carbowax are heated to 75°C. Carbowax #1540 is premelted and added to the phase B ingredients at 75°C until all the ingredients are dissolved. Add Phase B to Phase A with agitation. Place the mixed Phases A plus B under vacuum for 15 minutes with mixing. Add ZEO 49 (Phase C) with mixing. Place Phases A, B and C under vacuum with mixing for 15 minutes. Add half of the ZEOTHIX 265 with mixing. Mix Phases A, B, C and D under vacuum. Add the other half of Phase D with mixing. Vacuum this mixture for 15 minutes. Phase E is made by sprinkling sodium lauryl sulfate into the glycerine with agitation. The remaining ingredients of Phase E are added with agitation. After complete mixing phas E is added to Phases A, B, C and D with agitation to produce a gel dentifrice.

EXAMPLE 2 - GEL DENTIFRICE

NO.	PHASE	INGREDIENT	% BY WEIGHT
1	A	GLYCERINE 96%	11.5
2	A	CARBOXYMETHYL CELLULOSE (CMC 7MFX-HERCULES)	0.5
3	A	SORBITOL 70%	52.8
4	A	SILICA GELLANT ZEOSYL 200	5.00
5	A	SILICA ABRASIVE ZEODENT 113	15.0
6	B	SODIUM LAURYL SULFATE	1.20
7	B	POLYGLYCOL E1450NF DOW CHEMICAL)	3.00
8	B	SODIUM BENZOATE	2.00
9	B	TWEEN 20	0.80
10	B	SODIUM SACCHARIN USP	0.04
11	B	FLAVOR	0.66
12	B	TAP WATER	2.70
13	B	SORBITOL, 70%	4.80
	TOTAL		100.00%

Procedure: Pre-weigh all the ingredients of phase B flavor except flavor and mix flavor except flavor with agitation. Heat this mixture to 60°C and agitate to dissolve all the ingredients. After these ingredients are dissolved, then add the flavor. Pre-mix all the ingredients of phase A at room temperature at high speed. Add phase B ingredients. Mix at room temperature on low speed and mix for an additional time period until a gel-like product is formed. Put the thoroughly mixed product into an oven at 45°C for 72 hours.

EXAMPLE 3 - GEL DENTIFRICE

NO.	PHASE	INGREDIENT	% BY WEIGHT
1	A	LAPONITE XLG	3.00
2	A	GLYCERINE 96%	15.00

3	A	SORBITOL 70%	53.15
4	B	SODIUM SACCHARIN	0.005
5	B	XANTHAN GUM (KELTROL T)	0.03
6	B	ALLANTOIN	0.2
7	B	SODIUM BORATE	0.2
8	B	SODIUM BENZOATE	2.0
9	B	SODIUM SALICYLATE	0.2
10	B	SODIUM MONOFLUORO-PHOSPHATE	0.83
11	B	DEIONIZED WATER	4.33
12	C	SYLOID 74	12.00
13	C	CARBOXYMETHYL CELLULOSE (CMC 7MFX - HERCULES)	0.15
14	D	D&C RED #40 (1% Aqueous)	0.90
15	D	SODIUM LAURYL SULFATE	1.50
16	D	SORBITOL 70%	5.50
17	E	FLAVOR	1.00
	TOTAL		100.00%

Procedure: Mix glycerine and sorbitol together. Sprinkle LAPONITE into glycerine/sorbitol mixture with agitation. Heat this mixture to 70°C. Hold at 70°C with agitation for 20 min. Transfer to vacuum mixer. Add the ingredients of phase B one at a time, with agitation. Add the ingredients of phase C, mix under vacuum for 30 min. Prepare phase D by warming if necessary and then add to batch. Mix with slow agitation and then place under vacuum for 5 min. Add phase E. Mix under vacuum for 5 min.

EXAMPLE 4 - GEL DENTIFRICE

NO.	PHASE	INGREDIENT	% BY WEIGHT
1	A	SORBITOL 70 N/C	47.115
2	A	DEIONIZED WATER	2.45
3	A	SODIUM SACCHARIN	0.005
4	A	KELTROL T (XANTHAN GUM)	0.030
5	A	ALLANTOIN	0.20
6	A	SODIUM BENZOATE	2.0

7	A	SODIUM SALICYLATE	0.20
8	A	SODIUM BENZOATE	4.00
9	A	SODIUM MONOFLUOROPHOSPHATE	0.80
10	A	SODIUM SACCHARINE	0.30
11	B	CARBOWAX 1450	5.00
12	C	SILODENT 750	15.00
13	C	ZEOSYL 200	8.00
14	D	GLYCERINE 96%	5.00
15	D	CMC 9M31 XF	0.30
16	E	SORBITOL 70 N/C	5.00
17	E	SODIUM LAURYL SULFATE	1.50
18	E	FLAVOR	0.50
19	E	ALCOHOL SD38B	2.00
20	E	FD&C RED #40 (1%)	0.60
TOTAL			100.00

Procedure: Heat sorbitol & water to 75 degrees C. Mix ingredients 3, 4, 5, 6 and 7 separately to form a homogenous mixture. Add the balance of phase A, mixing thoroughly. When this mixture turns clear, transfer to vacuum mix. Thoroughly mix the Carbowax into the pre-mixed Phase A ingredients. Pre-mix the Silodent 750 and Zeosyl 200 and add to the mixture of A and B. Add phase C mix under vacuum for 20 minutes. Add glycerine and CMC 9M31XF and mix under vacuum for 10 minutes. Mix the sorbitol and sodium lauryl sulfate and heat to 70C. Mix until dissolved. Cool this to 30C. Add flavor, alcohol, & color. Add this mixture very slowly with gentle mixture.

EXAMPLE 5 - CHEWING GUM

INGREDIENT	% BY WEIGHT
GUM BASE	About 5% to about 95%
BINDER	0% to about 80%
FILLER	0% to about 90%
SUCROSE CORN SYRUP, or HYDROGEN ATED STARCH HYDROLYSATE	0% to about 95%
ARTIFICIAL SWEETENER	0% to about 1%
FLAVORANT	about 0.005% to about 5%
SODIUM BENZOATE	about 2% to about 15%
SODIUM LAURYL	about 0.1% to about 20%

SULFATE	
POLYSORBATE	0% TO ABOUT 5%
SODIUM SALICYLATE	0.2% to about 2%
PLASTICIZER	about 1% to about 20%
WATER	0% to about 10%

Procedure: Mix sodium benzoate, sodium lauryl sulfate and sodium salicylate into solution by adding water or plasticizer. Mix gum base, binder, filler and other ingredients thoroughly. Add the solution of sodium benzoate, sodium lauryl sulfate and sodium salicylate thoroughly with agitation into gum base. Roll gum base out and cut into strips of gum or small squares to be coated.

EXAMPLE 6 - LOZENGE

INGREDIENT	% BY WEIGHT
SORBITOL	0% to about 97.7%
MANNITOL	0% to about 97.7%
GUM ACACIA OR TRAGACANTH	0% to about 95%
SUGAR CORN SYRUP OR HYDROGENATED STARCH HYDROLYSATE	0% to about 97.7%
ARTIFICIAL SWEETENER	0% to about 1%
FLAVOR	0% to about 2%
SODIUM BENZOATE	about 2% to about 15%
SODIUM LAURYL SULFATE	about 0.1% to about 20%
POLYSORBATE	0% to about 5%
SODIUM SALICYLATE	about 0.2% to about 2%
TABLETTING LUBRICANT OR PLASTICIZER	0% to about 10%
WATER	0% to about 10%

Procedure: Dissolve sodium benzoate, sodium lauryl sulfate and sodium salicylate in water or solubilize with tableting liquid or plasticizer. Mix other dry ingredients together to form a homogeneous powder. Add

the solution of sodium benzoate, sodium lauryl sulfate, and sodium salicylate to the homogenous dry mix and mix thoroughly. This formula can then be introduced into a tableting machine to form the final lozenge product, or water or tableting lubricant can be added to form a dough. The dough can be rolled out or flattened, cut into lozenges, and dried.

EXAMPLE 6

DENTURE CLEANSER

INGREDIENT	% BY WEIGHT
SODIUM BENZOATE	about 2% to about 15%
SODIUM SALICYLATE	about 0.2% to about 6%
SODIUM LAURYL SULFATE	about 0.1% to about 20%
ALLANTOIN	about 0.1% to about 3%
SODIUM BORATE	about 0.2% to about 10%
CITRIC ACID	0% to about 30%
SODIUM PERBORATE	about 2% to about 25%
SODIUM PERSULFATE	about 2% to about 25%
SODIUM BICARBONATE	about 20% to about 50%
COLOR	0% to about 2%
FLAVOR	0% to about 4%

Procedure: Mix all the ingredients together to form a homogeneous powder. The powder can then be packaged, or formulated into tablets.

This invention has been described in terms of specific embodiments set forth in detail herein, but it should be understood that these are by way of illustration and the invention is not necessarily limited thereto. Modifications and variations will be apparent from the disclosure and may be resorted to without departing from the spirit of the invention as

those of skill in the art will readily understand. Accordingly, such variations and modifications are considered to be within the purview and scope of the invention and the following claims.

We claim:

1. A composition for loosening, removing and preventing the build-up of plaque on dental surfaces and for removing stains from dental surfaces comprising:

(a) effective amounts of an orally compatible surfactant;

(b) at least about 1% by weight of a benzoic acid salt; and

(c) a carrier for administering said surfactant onto dental surfaces wherein said benzoic acid salt and surfactant are uniformly dispersed or dissolved in said carrier.

2. The composition according to claim 1 wherein said carrier is a gel, paste, or powder vehicle and applicable to said dental surfaces by means of a toothbrush.

3. The composition according to claim 1 wherein said carrier is a lozenge.

4. The composition according to claim 1 wherein said carrier is a powder and said composition comprises a denture cleanser.

5. The composition according to claim 1 wherein said composition further comprises minor

effective amounts of a colorant and flavorant.

6. The composition according to claim 2 wherein said composition further comprises minor effective amounts of a compatible compatible substantive biocide.

7. The composition according to claim 6 wherein said substantive biocide is chlorhexidine, derivatives of chlorhexidine, or a pharmacologically acceptable salt or ester thereof.

8. The composition according to claim 7 wherein said substantive biocide comprises about 0.005% to about 0.75% by weight of said composition.

9. The composition according to claim 1 wherein said composition further comprises effective amounts of sodium monofluorophosphate or sodium fluoride or sodium fluoride.

10. The composition according to claim 5 wherein said composition further comprises effective amounts of an antiseptic other than a substantive biocide.

11. The composition according to claim 1 wherein said oral surfactant comprises about .1% to

about 10% by weight of said composition.

12. The composition according to claim 11 wherein said oral surfactant is non-ionic.

13. The composition according to claim 11 wherein said oral surfactant is anionic.

14. The composition according to claim 11 wherein said oral surfactant is amphoteric.

15. The composition according to claim 11 wherein said oral surfactant is cationic.

16. The composition according to claim 13 wherein said oral surfactant is sodium lauryl sulfate.

17. The composition according to claim 16 wherein said oral surfactant comprises about 0.5% to about 10% of said composition.

18. The composition according to claim 16 wherein said composition further comprises emulsifiers and bulking agents.

19. The composition according to claim 18 wherein said composition further comprises an abrasive agent.

20. The composition according to claim 19 wherein said abrasive agent is a silica xerogel, and said composition comprises a toothpaste.

21. The composition according to claim 20 wherein said abrasive agent comprises about 5% to about 25% by weight of said composition.

22. The composition according to claim 10 wherein said antiseptic is sodium salicylate.

23. The composition according to claim 22 wherein said antiseptic comprises about 0.2% to about 1% by weight of said composition.

24. The composition according to claim 23 wherein said composition further comprises allantoin as a healing agent.

25. The composition according to claim 24 wherein said healing agent comprises about 0.1% to about 3.0% by weight of said composition.

26. The composition according to claim 17 wherein said composition further comprises a plasticizer.

27. The composition according to claim 26

wherein said plasticizer is a polyethylene glycol, glycerine, or sorbitol.

28. The composition according to claim 27 wherein said plasticizer comprises about 5% to about 45% by weight of the dentifrice.

29. The composition according to claim 18 wherein said sodium benzoate comprises at least about 2% by weight of said dentifrice.

30. The composition according to claim 3 wherein said carrier is comprised of binders and fillers.

31. The composition according to claim 30 wherein said binders are natural and synthetic gums.

32. The composition according to claim 31 wherein said natural gums are selected from the group consisting of gum acacia and tragacanth.

33. The composition according to claim 30 wherein said fillers are selected from the group consisting of mannitol and sorbitol.

34. The composition according to claim 31 wherein said binders and fillers comprise about 40% to

about 97.5% of said composition.

35. The composition according to claim 34 further comprising a flavorant, a colorant, and an artificial sweetener.

36. The composition according to claim 35 wherein said artificial sweetener comprises about 0.005% to about 1% by weight.

37. The composition according to claim 36 wherein said sodium benzoate comprises at least about 2% by weight.

38. The composition according to claim 4 wherein said composition further comprises effective amounts of an oxygen releasing compound.

39. The composition according to claim 38 wherein said oxygen releasing compound is a salt of perborate or persulfate.

40. The composition according to claim 39 wherein said oxygen releasing compound comprises about 5% to about 17% by weight of said composition.

41. The composition according to claim 40 wherein aid composition further comprises a detergent

builder.

42. The composition according to claim 41 wherein aid detergent builder is sodium borate.

43. The composition according to claim 42 wherein said composition further comprises an antiseptic other than a substantive biocide.

44. The composition according to claim 43 wherein said antiseptic is sodium salicylate.

45. The composition according to claim 44 wherein said antiseptic comprises about 0.1% to about 6% by weight of said composition.

46. The composition according to claim 45 wherein said composition further comprises an organic acid.

47. The composition according to claim 46 wherein said organic acid is citric acid.

48. The composition according to claim 45 wherein said composition further comprises effective amounts of a gas emitting substance which produces effervescence upon exposure to an acidic solution.

49. The composition according to claim 48 wherein said gas emitting substance is sodium bicarbonate.

50. The composition according to claim 46 wherein said sodium benzoate comprises at least about 2% by weight of said composition.

51. The composition according to claim 46 wherein said sodium benzoate comprises about 4% to about 15% by weight of said composition.

52. A method of oral hygiene to loosen, remove and prevent the build-up of plaque on dental surfaces comprising exposing the dental surfaces to a composition comprised of:

(a) effective amounts of an orally compatible surfactant;

(b) at least about 1% by weight of a benzoic acid salt; and

(c) a carrier for administering said surfactant onto said dental surfaces wherein said benzoic acid salt and oral surfactant are uniformly dispersed or dissolved in said carrier.

53. The method according to claim 52 wherein said carrier is a gel, paste or powder vehicle and applicable to said dental surfaces by means of a

toothbrush.

54. The method according to claim 53 wherein said carrier is a lozenge.

55. The method according to claim 52 wherein said carrier is a powder and said composition comprises a denture cleanser.

56. The method according to claim 52 wherein said orally compatible surfactant is sodium lauryl sulfate.

57. The method according to claim 52 wherein said orally compatible surfactant comprises about 0.1% to about 10% by weight of said composition.

58. The method according to claim 57 wherein said composition further comprises minor effective amounts of a colorant and flavorant.

59. The method according to claim 52 wherein said composition further comprises minor effective amounts of a substantive biocide.

60. The method according to claim 59 wherein said substantive biocide is chlorhexidene.

61. The method according to claim 60 wherein said substantive biocide comprises about 0.005% to about 0.75% by weight of the composition.

62. The method according to claim 58 wherein said composition further comprises effective amounts of sodium monofluorophosphate.

63. The method according to claim 58 wherein said composition further comprises a detergent builder.

64. The method according to claim 63 wherein said detergent builder is sodium borate.

65. The method according to claim 63 wherein said composition comprises effective amounts of an abrasive agent.

66. The method according to claim 65 wherein said composition comprises effective amounts of an antiseptic.

67. The method according to claim 66 wherein said antiseptic comprises about 0.2% to about 1% by weight of said composition.

68. The method according to claim 54 wherein said carrier is comprised of binders and fillers.

69. The method according to claim 68 wherein said binders and fillers comprise about 40% to about 97.7% of said composition.

70. The method according to claim 69 wherein said composition further comprises a flavorant, a colorant, and an artificial sweetener.

71. The method according to claim 69 wherein said sodium benzoate comprises at least about 2% by weight of said composition.

72. The method according to claim 55 wherein said composition is further comprised of effective amounts of an oxygen releasing compound.

73. The method according to claim 69 wherein said oxygen releasing compound is the sodium salt of perborate or persulfate.

74. The method according to claim 73 wherein said oxygen releasing compound comprises about 5% to about 17% by weight of said composition.

75. The method according to claim 74 wherein said composition further comprises a detergent builder.

76. The method according to claim 75 wherein

said detergent builder is sodium borate.

77. The method according to claim 76 wherein said composition further comprises an antiseptic.

78. The method according to claim 77 wherein said antiseptic is sodium salicylate.

79. The method according to claim 78 wherein said composition further comprises an organic acid.

80. The method according to claim 79 wherein said organic acid is citric acid.

81. The method according to claim 79 wherein said composition further comprises effective amounts of a gas emitting substance which produces effervescence upon exposure to an acidic solution.

82. The method according to claim 80 wherein said as emitting substance is sodium bicarbonate.

83. The method according to claim 82 wherein said sodium benzoate comprises at least about 2% by weight of said composition.

84. The method according to claim 83 wherein said sodium benzoate comprises about 4% to about 15% by

weight of said composition.

85. A method of oral hygiene to remove stains on dental surfaces comprising exposing the dental surfaces to a composition comprised of:

(a) effective amounts of an orally compatible surfactant;

(b) at least 1% by weight of a benzoic acid salt; and

(c) a carrier for administering said surfactant onto said dental surfaces wherein said benzoic acid salt and oral surfactant are uniformly dispersed or dissolved in said carrier.

86. The method according to claim 85 wherein said orally compatible surfactant is sodium lauryl sulfate.

87. The method according to claim 86 wherein said orally compatible surfactant comprises about 0.1% to about 1% by weight of said composition.

88. The method according to claim 85 wherein said carrier is a gel, paste, or powder vehicle and applicable to aid dental surfaces by means of a toothbrush.

89. The method according to claim 88 wherein

said composition is comprised of at least about 6% by weight sodium benzoate.

90. The method according to claim 85 wherein said carrier comprises a lozenge.

91. The method according to claim 85 wherein said carrier is a powder and said composition comprises a denture cleanser.

92. A dentifrice composition for loosening removing and preventing the build-up of plaque on dental surfaces and for removing stains from dental surfaces comprising:

(a) effective amounts of an orally compatible surfactant;

(b) at least about 6% by weight of a benzoic acid salt;

(c) a carrier for administering said surfactant onto dental surfaces wherein said benzoic acid salt and surfactant are uniformly dispersed or dissolved in said carrier.

93. The composition according to claim 92 wherein said carrier is a gel, paste, or powder vehicle and applicable to said dental surfaces by means of a toothbrush.

94. The composition according to claim 93 further comprising an abrasive agent.

95. The composition according to claim 94 further comprising effective amounts of a colorant and flavorant.

96. The composition according to claim 95 wherein said substantive biocide is chlorhexidine, derivatives of chlorhexidine, or a pharmacologically acceptable salt or ester thereof.

97. The composition according to claim 92 wherein said composition further comprises effective amounts of sodium fluoride.

98. The composition according to claiim 92 wherein said oral surfactant comprises about .1% to about 10% by weight of said composition.

99. The composition according to claim 92 wherein said oral surfactant is sodium lauryl sulfate.

100. The composition according to claim 99 wherein said oral surfactant comprises about 0.5% to about 6% of said composition.

101. The composition according to claim 94 wherein said abrasive agent comprises about 5% to about 25% by weight of said composition.

102. The composition according to claim 92 wherein the pH of said composition is in the range of about 6.0 to about 8.0.

103. The composition according to claim 92 wherein the pH of said composition is in the range of about 6.0 to 7.0.

INTERNATIONAL SEARCH REPORT

International Application No PCT/US87/01640

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

U.S.CL.: 424/43; 424/44; 424/49; 424/52; 424/53; See Continuation.
IPC 4): A61K 7/16; A61K 7/18; A61K 7/20; A61K 7/24; A61K 9/00

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System [5]	Classification Symbols
US	424/49; 424/52; 424/53; 424/55; 424/56, 424/57; 424/58; 424/43; 424/44

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [6]

CAS; APS

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category [15]	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
Y	U.S., A, 2,054,742 (ELBEL) 15 September 1936 (15.09.36) (Note Example 1 and claim 18).	1-6, 10-11, 13,16-17, 30-32,38, 52-59, 85-91
Y	U.S., A, 3,887,701 (NACHTIGAL) 03 June 1975 (03.06.75) (Note columns 1, 3 and 4 lines 23-26, 27-58, 12-39, respectively).	1-8,10, 11-21, 26-28, 30-36, 53-61, 63-70, 85-91
Y	U.S., A, 4,362,639 (EOGA) 07 December 1982 (07.12.82) (Note column 2 Summary of the Invention and Table 1).	1,4, 38-47, 72-80
A	U.S., A, 1,627,963 (FULLER) 10 May 1927 (10.05.27) (Note column 3, lines 22-29).	5,10, 22-23

* Special categories of cited documents: [19]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]

21 SEPTEMBER 1987

Date of Mailing of this International Search Report [2]

09 OCT 1987

International Searching Authority [1]

ISA/US

Signature of Authorized Officer [20]

Fatemeh Moezie

Fatemeh Moezie

PCT/US87/01640

I. CLASSIFICATION OF SUBJECT MATTER (CONTINUED)

U.S. 424/55; 424/56; 424/57; 424/58

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

Y	U.S., A, 3,772,431 (MIKVY) 13 November 1973 (13.11.73) (Note column 2, lines 29-33).	46-49, 79-82
Y	U.S., A, 4,154,815 (PADER) 15 May 1979 (15.05.79) (Note column 6, lines 1-29 and example 4).	1-21, 26-37, 52-71, 83-103

V.☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [10]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1.☐ Claim numbers . because they relate to subject matter [12] not required to be searched by this Authority, namely:

2.☐ Claim numbers . because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [13], specifically:

VI.☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [11]

This International Searching Authority found multiple inventions in this international application as follows:

1.☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2.☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3.☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims: it is covered by claim numbers:

4.☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No [18]
X, P Y	U.S., A, 4,666,708 (GOLDEMBERG) 19 May 1987 (19.05.87) (Note Detailed Description of the Invention).	1,5,10-18, 26-29, 38-50, ~~52,57-61,~~ 63-64, 85-87
X Y	U.S., A, 4,585,649 (LYNCH) 29 April 1986 (29.04.86) (Note Abstract and column 2 line 57 to column 4, line 11 and column 7, lines 16 to Example 31-45).	1-3,5-7, 9-29, 52-63, 65-71, 85-91 ~~4,8,30-51,~~ 64,72-84, 92-103
Y	GB, A,2,095,694A (ELLIS) 06 October 1982 (06.10.82) (Note page 2, the example).	38-51, 71-84
X Y	SE, A 321,765 Holmstron 16 March 1970 (16.03.70) (Note the example on pages 3 and 4 of the English language translation).	1,5,9,11, 13 ~~2-4,6-8,~~ 10,12, 14-103
Y	Chemical Abstracts, Volume 94, 1981, SKLYAR, "Toothpaste", Abst. No. 197571g.	1,2,5
Y	Chemical Abstracts, Volume 78, 1973, KONSTANTINOV, "Toothpaste", Abst. No. 62202m.	1,2,5,11, 13,16-19, 26-37